A randomized prospective trial comparing different regimens of oral sodium phosphate and polyethylene glycol–based lavage solution in the preparation of patients for colonoscopy

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Background: Regulatory agencies have warned clinicians regarding the risk of electrolyte abnormalities if more than two 45-mL bottles of oral sodium phosphate (NaP) solution are administered within a 24-hour period.

Objective: To compare the efficacy, safety, and tolerability of different regimens of oral NaP and polyethylene glycol (PEG).

Design: Randomized controlled trial.

Setting: Teaching hospital outpatient endoscopy clinic.

Patients: Two hundred outpatients without comorbidities who underwent routine colonoscopy.

Interventions: Two bottles of NaP, 6, 12, or 24 hours apart; or 4 L PEG.

Main Outcome Measurements: Bowel preparation quality, patient tolerability, and electrolyte changes.

Results: The 12- and 24-hour NaP achieved better cleansing than the 6-hour NaP or PEG. Only 8.5% and 8.3% of patients in the 24- and 12-hour NaP had poor preparations, respectively, compared with 15.6% and 23.4% in the 6-hour NaP and PEG, respectively. The poorer preparation scores with PEG were partly because of a greater amount of colonic fluid. There were no relevant electrolyte changes with PEG, whereas hypokalemia, hypocalcemia, or hyperphosphatemia developed in 5% to 57% of patients on NaP. All regimens were poorly tolerated by patients.

Limitations: The study was likely underpowered to detect small group differences in electrolytes.

Conclusions: A 24- or 12-hour NaP bowel preparation strategy was more effective than NaP 6 hours apart or PEG. PEG use is associated with more residual colonic fluid but represents an alternative to NaP in some clinical situations. (Gastrointest Endosc 2006;64:544-52.)

Bowel preparation for colonoscopy remains a relatively unpleasant, if not difficult, process for many patients. Despite advances in endoscopic equipment, techniques, and sedation practices that have improved the tolerability of the procedure itself, patients must still ingest a preparation and adequate fluid to achieve proper bowel cleansing. Unfortunately, an ideal bowel preparation that is at the same time effective, tolerable, safe, and without contraindications has not yet been found. This is evidenced by the multiplicity of studies assessing and comparing various new and old bowel-preparation regimens. Furthermore, concerns have recently been voiced by the Food and Drug Administration and Health Canada regarding the safety of oral sodium phosphate (NaP) bowel preparations when two bottles are used within a period of less than 24 hours in patients with or without risk factors for electrolyte disturbances and/or fluid overload. Various studies have also warned of potential problems with oral NaP preparations, including hyperphosphatemia, hypocalcemia, hypokalemia, congestive heart failure, and renal failure.
studies, adverse events were seen in patients without significant comorbidities. Oral NaP preparations have been preferred by clinicians because of their small volume, and their previously documented superior efficacy over polyethylene glycol (PEG)–based preparations.\(^2\,6\,47\,51\,59\)

Furthermore, in many institutions, including ours, the prospect of giving two small (45 mL) bottles of oral NaP 6 or 12 hours apart was considered both effective and practical, considering the few hours required to achieve bowel preparation. This practice was popular, both in the inpatient setting, to rapidly cleanse the bowel of patients presenting for a lower GI bleed, as well as among outpatients. Lengthening the interval for administration of the two doses of NaP raised concerns among clinicians about the differential efficacy of the bowel preparation, the possible impact on patient acceptance and satisfaction, as well as the safety of the proposed preparation regimens.

The purpose of this study was to compare the efficacy, safety, and patient tolerability of 3 oral NaP strategies and 4 L PEG for bowel preparation.

**PATIENTS AND METHODS**

This study was approved by our institutional ethics review board and did not receive any industry funding.

All patients between the age of 18 and 80 years referred for colonoscopy at The Ottawa Hospital were considered for inclusion and were approached for consent by their gastroenterologists. Patients were excluded if they had known or suspected renal failure, unstable angina, acute coronary syndrome/congestive heart failure, ascites, megacolon, known or suspected bowel obstruction, or other comorbidities that may prevent colonoscopy. Patients were also excluded if they had a previous partial or subtotal colectomy, or if the colonoscopy was performed for the evaluation of diarrhea.

Randomization was conducted in blocks of 8 by using a computer-generated table, with allocation concealment maintained through the use of consecutively numbered sealed envelopes. Investigators and colonoscopists were blinded to group allocation. Patients were assigned to one of 4 groups: (1) oral NaP, 2 bottles (45 mL each) 6 hours apart; (2) oral NaP, 2 bottles 12 hours apart; (3) oral NaP, 2 bottles 24 hours apart; or (4) 4 L PEG. A study assistant assigned patients to their group and instructed them on the proper use of their assigned bowel-preparation method. Patients were given a tolerability questionnaire to be completed once their bowel preparation was finished and before coming to the hospital for the colonoscopy. This questionnaire was previously reported\(^58\) and was modified for this study. Patients were also instructed not to discuss their bowel preparation with their gastroenterologist but instead to contact the study assistant if questions arose. A mechanism was established to address patient concerns and issues of safety, without unblinding the gastroenterologist. A calibration exercise was conducted to ensure that the participating endoscopists understood and agreed on the rating of bowel-preparation quality by using the Ottawa bowel-preparation scale.\(^78\) This validated scale rates each of the right, the mid, and the rectosigmoid colon on a 5-point scale (0-4), as well as a global 3-point rating for overall colonic fluid. The total score ranges from 0 to 14. An excellent preparation with little fluid would score 0 to 1; a good preparation, 2 to 4; while scores higher than 4 would indicate progressively worsening bowel preparations. A completely unprepared colon would score 11 to 14, depending on the amount of colonic fluid.

The bowel preparations were started within 30 hours of the colonoscopy, depending on the study arm. Colonoscopy was performed in a standard manner. The endoscopists rated the bowel-preparation quality during the procedure and recorded the results on a separate standardized form.

**Statistical analysis**

On the basis of data from our previous study,\(^78\) a sample size of 200 patients was estimated to give an 80% power at a two-sided alpha of 0.05 to detect a 1.5-point difference in the Ottawa bowel-preparation quality scale. Some patients did not contribute data for some secondary end points. Mean differences between groups were analyzed by using analysis of variance with correction for multiple comparisons. Analyses were adjusted for the time of the endoscopy (morning or afternoon) and as a sensitivity analysis for the endoscopist. Categorical variables in the tolerability questionnaire were analyzed by using the Kruskal-Wallis test.
RESULTS

Of the 200 randomized patients, 193 completed the study. Four patients drank the wrong preparation, one required urgent surgery for obstructing carcinoma, while the others declined colonoscopy. The baseline characteristics and the indications for colonoscopy are presented in Table 1. There were no significant group differences detected except for a trend toward greater volume ingestions in the PEG group. The most common reasons for colonoscopy were screening/surveillance and change in bowel habit (diarrhea excluded).

Bowel-preparation quality

All preparation strategies produced a reasonably good bowel cleansing, with all groups showing mean total Ottawa preparation scores of less than 3.5 (Table 2). The right colon was consistently more difficult to clean, with segment scores of 1.14 to 1.59 of 4 (between good and fair), with no significant group differences. For the remaining colonic segments and for the total preparation score, the 12- and 24-hour NaP groups produced better cleansing than the 6-hour NaP group or the PEG group (Table 2 and Fig. 1). Only 8.5% and 8.3% of patients in the 24-hour and the 12-hour NaP groups had poor preparations, respectively, compared with 15.6% and 23.4% of patients in the 6-hour NaP group and the PEG group, respectively. Significantly greater residual colonic fluid was seen with PEG than the other preparation groups ($p < 0.005$).

Laboratory changes

Changes in laboratory values from pre-preparation baseline were commonly seen. However, none of the enrolled patients developed clinically overt manifestations of these changes. No important changes occurred in the complete blood cell count (CBC), sodium (Na), urea, or creatinine in any patient. As a whole, all oral NaP groups were associated with statistically significant changes in serum potassium ($K^+$), calcium (Ca), and phosphate ($PO_4$) from baseline. PEG was associated with minimal changes in these electrolytes and had statistically less change than each of the oral NaP groups (Table 3).

As outlined in Table 4, no patients in the PEG group developed “important” electrolyte changes in Na, $K^+$, ionized Ca, or $PO_4$. However, some patients in the oral NaP groups developed important electrolyte changes. In particular, 10% to 13% of patients taking oral NaP developed hypokalemia ($K^+ < 3.0$), compared with none in the PEG group (statistically significant for PEG vs oral NaP groups; statistical significance lost for group comparisons after correction for multiple comparisons). As well, 39% to 57% of oral NaP subjects developed hypocalcemia (total serum Ca) compared with 26% with PEG (statistical significance maintained only for PEG vs 24-hour NaP after correction for multiple comparisons). Finally, 5% to 12% of patients taking oral NaP developed hyperphosphatemia ($PO_4 > 2.0$ mmol/L) compared with none in the PEG group.

In a post hoc general linear model analysis, we found that, in healthy outpatients, age was not a predictor of electrolyte abnormalities (hypokalemia [$p = 0.192$], or hyperphosphatemia [$p = 0.117$]).
Patient tolerability

As shown in Tables 5 and 6, as a whole, the various bowel preparations were generally not well tolerated by patients. Although fewer patients rated the taste of PEG poorly compared with the oral NaP preparations ($p = 0.027$), 80% of them still felt that its taste was worse than “tolerable.” Furthermore, 65% to 82% of patients in the studied groups had moderate or great difficulty drinking the preparation (no significant group differences). There was a nonsignificant trend toward fewer patients being able to complete the PEG preparation than the oral NaP preparations, and significantly more people would refuse PEG if offered again compared with the oral NaP groups ($p < 0.010$). Significantly fewer people would refuse the 24-hour NaP preparation than the other oral NaP regimens ($p < 0.022$).

Patients in the 6-hour oral NaP and the PEG groups missed less time off work than those in the 12- and 24-hour NaP groups. In the 24-hour NaP group, 28% of patients missed 2 days of work (excluding the day of the colonoscopy).

Nausea, abdominal pain, and bloating were commonly experienced by patients in all preparation groups. The percentage of patients experiencing more than mild symptoms is listed in Table 6. We identified no statistically significant group differences for any of these symptoms, except for dizziness, which occurred significantly more common in patients taking the 6-hour NaP preparation ($p = 0.012$).

DISCUSSION

The results of this study demonstrate that all the studied bowel-preparation strategies were generally effective at producing at least fair-to-good bowel cleansing. As a group, the oral NaP strategies produced a better bowel preparation than a PEG-based strategy, and longer preparation times within the oral NaP groups were associated with better preparation quality. Although electrolyte abnormalities were commonly seen, particularly in the oral NaP groups, none of our study patients suffered any clinical adverse events. Last, the tolerability of all 4 preparation regimens was relatively poor.

We had hypothesized that rapid bowel preparation with two oral NaP bottles given 6 hours apart would produce the most effective cleansing. However, it appears that longer preparation times produced better bowel preparation, most likely because of the greater potential for oral fluid intake. Oral NaP bottles taken 12 to 24 hours apart were more effective than oral NaP taken 6 hours apart or

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**Figure 1.** Percentage of patients with poor preparation quality. Poor quality is defined as a total Ottawa Prep score of greater than 5 (includes fair, poor, and inadequate scores). A good preparation score would include colon-segment scores rated as excellent or good, and not more than one colon segment rated as fair.
PEG. We saw a trend toward greater fluid intake, with longer preparation times, which likely explains, in part, the poor showing of the 6-hour NaP group (Table 1).

Other studies have also suggested that oral NaP is more effective than PEG-based lavage solutions. However, in our study, the apparent inferiority of PEG in this setting was, in part, related to a greater quantity of fluid remaining in the colon, instead of strictly from fecal soiling.

In general, the studied bowel-preparation strategies were less effective at cleansing the right colon than the other segments of the colon. There were no statistically significant differences between the strategies for this segment of the colon, although there was a trend toward a worse preparation with the 6-hour oral NaP strategy.

Mild, unimportant electrolyte abnormalities were commonly seen in this study. No important changes occurred in the CBC, Na, urea, or creatinine in any patient.

**TABLE 3. Biochemical data**

<table>
<thead>
<tr>
<th>Preparation group, mean difference</th>
<th>Oral NaP, 6 h</th>
<th>Oral NaP, 12 h</th>
<th>Oral NaP, 24 h</th>
<th>PEG</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na</td>
<td>–0.026</td>
<td>0.32</td>
<td>0.67</td>
<td>1.00</td>
<td>0.28</td>
</tr>
<tr>
<td>K⁺</td>
<td>–0.76</td>
<td>–0.84</td>
<td>–0.70</td>
<td>–0.37</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ca</td>
<td>–0.14</td>
<td>–0.13</td>
<td>–0.13</td>
<td>–0.080</td>
<td>0.037</td>
</tr>
<tr>
<td>ionized Ca</td>
<td>–0.029</td>
<td>–0.071</td>
<td>–0.064</td>
<td>–0.040</td>
<td>0.52</td>
</tr>
<tr>
<td>PO₄</td>
<td>0.32</td>
<td>0.37</td>
<td>0.28</td>
<td>–0.13</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cl</td>
<td>0.82</td>
<td>0.89</td>
<td>1.33</td>
<td>1.21</td>
<td>0.84</td>
</tr>
<tr>
<td>Serum urea nitrogen</td>
<td>–1.66</td>
<td>–1.28</td>
<td>–2.05</td>
<td>–0.99</td>
<td>0.001</td>
</tr>
<tr>
<td>Creatinine (µmol/L)</td>
<td>–0.23</td>
<td>0.68</td>
<td>–2.11</td>
<td>–2.23</td>
<td>0.33</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>–0.0069</td>
<td>–0.0011</td>
<td>–0.0067</td>
<td>0.0034</td>
<td>0.22</td>
</tr>
</tbody>
</table>

* A negative number represents a decrease in the post-lavage measurement.

| Significance difference between PEG and 6 h NaP (p < 0.001), between PEG and 12 h NaP (p < 0.001), and between PEG and 24 h NaP (p = 0.002). |
| Significant difference between PEG and 6 h NaP (p = 0.007), between PEG and 12 h NaP (p = 0.037), and between PEG and 24 h NaP (p = 0.031). |
| Significant difference between PEG and 6 h NaP (p < 0.001), between PEG and 12 h NaP (p < 0.001), and between PEG and 24 h NaP (p < 0.001). |
| Significant difference between PEG and 6 h NaP (p = 0.04), between PEG and 24 h NaP (p = 0.001), and between 12 h and 24 h NaPs (p = 0.03). |

**TABLE 4. Important electrolytes abnormalities**

<table>
<thead>
<tr>
<th>Preparation group n (%)</th>
<th>Oral NaP, 6 h</th>
<th>Oral NaP, 12 h</th>
<th>Oral NaP, 24 h</th>
<th>PEG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na &gt; 145 mmol/L</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Na &lt; 125 mmol/L</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>K⁺ &lt; 3.0 mmol/L</td>
<td>5 (13)</td>
<td>4 (10)</td>
<td>6 (13)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total Ca &lt; 2.2 mmol/L †</td>
<td>16 (42)</td>
<td>17 (39)</td>
<td>27 (57)</td>
<td>12 (26)</td>
</tr>
<tr>
<td>Ionized Ca &lt; 1.0 mmol/L</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>PO₄ &gt; 2.0 mmol/L</td>
<td>2 (5)</td>
<td>5 (12)</td>
<td>2 (5)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

* None of the studied patients demonstrated clinical manifestations of these electrolyte abnormalities.

† Overall significant group differences; however, only the comparison of PEG vs NaP 24 h maintains statistical significance after multiple comparison adjustment (p = 0.012).
Potentially important changes in $K^+$, $Ca$, and $PO_4$ were observed almost exclusively in the oral NaP groups, with PEG demonstrating a drop in total Ca in only 12% of patients in contrast to the 39% to 57% seen in the oral NaP groups. Important hypokalemia and hyperphosphatemia were strictly observed with oral NaP preparations. We did not observe any clinical manifestations of these electrolyte abnormalities, and no patient required specific treatment for these. Clearly, our study was not powered to detect clinical adverse events, particularly in the healthy patient population that we studied. Nonetheless, the finding of important hypokalemia in 10% to 13%, as well as hypocalcemia in 39% to 57% of these otherwise healthy subjects, should act as a warning regarding the use of oral NaP agents in a more typical patient group. We found no statistically significant differences in the occurrence of these electrolyte abnormalities between the different oral NaP groups. This is likely because of insufficient power to detect these differences, as electrolyte changes were not our primary end point. Also, this could be because all 3 NaP groups received the same dose of the solution (45 mL), albeit at different timings.

Hookey et al extensively reviewed the literature regarding the safety of oral PO$_4$ solutions. In their review, the investigators found that oral PO$_4$ solutions were generally safe and that most adverse events occurred when these agents were used in high doses or in patients with contraindications to their use, such as renal impairment or important comorbidities. The investigators cautioned against the use of oral NaP at intervals less than 5 to 12 hours apart and the use of more than two 45-mL bottles for bowel preparation. In light of these data, and the warnings from regulatory agencies, it is recommended that two 45-mL bottles of oral PO$_4$ solution be used 12 to 24 hours apart. Furthermore, on the basis of the results of the current study, this longer interval between bottles would be expected to produce the best preparation quality.

Bowel preparations are generally regarded as unpleasant by patients, despite the various products and additives that attempt to improve their taste and tolerability. It is not uncommon for patients to state that the preparation is worse than the actual colonoscopy. With this in mind, we hypothesized that perhaps a shorter preparation interval, with a small volume of purgative, would be preferred.

### TABLE 5. Tolerability of bowel preparation

<table>
<thead>
<tr>
<th>Preparation group n (%)</th>
<th>Oral NaP, 6 h</th>
<th>Oral NaP, 12 h</th>
<th>Oral NaP, 24 h</th>
<th>PEG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taste (worse than tolerable)*</td>
<td>41 (93)</td>
<td>47 (98)</td>
<td>40 (87)</td>
<td>35 (80)</td>
</tr>
<tr>
<td>Preparation difficulty (moderate or greater)</td>
<td>34 (77)</td>
<td>31 (65)</td>
<td>36 (80)</td>
<td>36 (82)</td>
</tr>
<tr>
<td>Could not drink all preparation</td>
<td>6 (14)</td>
<td>3 (6)</td>
<td>3 (7)</td>
<td>9 (21)</td>
</tr>
<tr>
<td>Refuse preparation in future</td>
<td>6 (14)</td>
<td>5 (11)</td>
<td>1 (2)</td>
<td>10 (23)</td>
</tr>
<tr>
<td>Time off work</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Half day or less</td>
<td>20 (67)</td>
<td>15 (46)</td>
<td>15 (51)</td>
<td>19 (83)</td>
</tr>
<tr>
<td>1 d</td>
<td>10 (33)</td>
<td>16 (49)</td>
<td>6 (21)</td>
<td>3 (13)</td>
</tr>
<tr>
<td>2 d</td>
<td>0 (0)</td>
<td>2 (6)</td>
<td>8 (28)</td>
<td>1 (4)</td>
</tr>
</tbody>
</table>

*PEG was associated with statistically fewer reports of intolerable taste ($p = 0.027$).
| Nonsignificant trend toward less preparation difficulty with 12 h NaP ($p = 0.20$). |
| Nonsignificant trend toward less PEG preparation completion ($p = 0.20$). |
| Significantly more people would refuse PEG if offered again compared with the oral NaP groups ($p = 0.010$) and oral 24-h NaP group was preferred over the other oral NaP groups ($p = 0.044$). |
| PEG and 6-h NaP groups are associated with significantly less time off work ($p = 0.018$). |

### TABLE 6. Symptoms greater than mild

<table>
<thead>
<tr>
<th>Preparation group n (%)</th>
<th>Oral NaP, 6 h</th>
<th>Oral NaP, 12 h</th>
<th>Oral NaP, 24 h</th>
<th>PEG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>12 (27)</td>
<td>13 (28)</td>
<td>8 (17)</td>
<td>7 (17)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0 (0)</td>
<td>2 (4)</td>
<td>2 (4)</td>
<td>5 (11)</td>
</tr>
<tr>
<td>Abdominal cramps</td>
<td>4 (9)</td>
<td>5 (10)</td>
<td>6 (13)</td>
<td>7 (16)</td>
</tr>
<tr>
<td>Bloating</td>
<td>7 (16)</td>
<td>7 (15)</td>
<td>12 (27)</td>
<td>12 (26)</td>
</tr>
<tr>
<td>Chest pain</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Dizziness*</td>
<td>7 (16)</td>
<td>2 (4)</td>
<td>0 (0)</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

*Only dizziness maintains statistical significance after correction for multiple comparisons ($p = 0.012$) for the 6-h NaP group.
by patients, both from the perspective of “getting it over quickly,” and from minimizing time lost from work or other commitments. The results of our study did not shed any clear light on these issues. On the one hand, we documented more time lost from work with the 24-hour preparation strategy compared with the other strategies, as would be expected, but overall tolerability for all the strategies was poor at best. For example, fewer patients rated the taste of PEG as “worse than tolerable” than the other preparations, but still, 80% of those taking PEG rated it that way. Approximately 80% of patients in all groups reported more than moderate difficulty taking the purgative. Although 65% of those in the 12-hour NaP group reported it as such, this lower value was not statistically different from those of the other groups. More patients in the PEG group had greater difficulty completing the preparation and would refuse the preparation if given to them again. Other studies have also generally found that oral PO₄ preparations, with their smaller volumes, are better tolerated than PEG-based solutions.²⁻⁶,¹¹⁻⁵⁹ But, it is interesting to note that patients in our study generally preferred the taste of the PEG, so the poor tolerability of this strategy likely reflects the requirement of drinking the entire 4-L volume. Others have found that 2 L PEG plus a laxative was better tolerated and more effective than 4 L PEG.¹¹ So it is possible that a 2 L PEG strategy would have shown a better taste and less difficulty completing the preparation.

In conclusion, we set out to determine whether prolonging the bowel-preparation interval on the basis of current recommendations would result in a negative impact on the preparation quality or patient preference. Our findings suggest that prolonging the bowel preparation interval to 12 or 24 hours between bottles with oral NaP products is associated with an improved preparation quality, though at the cost of more time lost from work compared with a 6-hour strategy. Given that the regulatory agencies, and others, have identified a greater risk of electrolyte abnormalities with short preparation intervals,⁶⁻²⁻⁶,⁷⁰ and that our own study demonstrated important electrolyte abnormalities even in subjects without comorbidities, we recommend that a 12- to 24-hour bowel-preparation strategy for NaP be adopted for routine outpatient colonoscopies. We found no difference in bowel quality or electrolyte changes between the 24- and 12-hour NaP groups. This may represent a true absence of a difference, but, because important electrolyte changes are relatively rare, it is likely that this represents insufficient power to detect a difference. The 24-hour NaP group required more time off work, which is another consideration in choosing between the 12- and 24-hour NaP strategies. Further study will be required to clarify these issues. Although PEG produced a somewhat poorer preparation quality, this was, in part, because of residual colonic fluid, and, given its electrolyte safety, it may be considered as an alternative to NaP in some clinical situations. Last, the results of this study apply to routine outpatient colonoscopies. Inpatients and those undergoing colonoscopy for acute-GI bleeding represent distinct clinical entities with individualized preparation protocols.

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DISCLOSURE

The authors have no disclosures to make.

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